

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

ABBOTT CARDIOVASCULAR)	
SYSTEMS, INC. and ABBOTT)	
LABORATORIES, INC.,)	
Plaintiffs,)	
)	Civil Action No. 98-80 (SLR)
v.)	(Consolidated with C.A. No. 98-314 (SLR) and
)	C.A. No. 98-316 (SLR))
)	
MEDTRONIC VASCULAR, INC. and)	REDACTED PUBLIC VERSION
MEDTRONIC USA, INC.)	
Defendants.)	
)	
)	

DECLARATION OF DAVID L. PEARLE, M.D.

I, David L. Pearle, hereby declare as follows:

1. I am a medical doctor specializing in the field of clinical and interventional cardiology. I currently serve as a Professor of Medicine at Medstar Georgetown University Hospital in Washington, DC. Along with my teaching responsibilities at Georgetown University, I am the Director of the Coronary Care Unit, Georgetown University Hospital, a position I have held since 1995.

2. I graduated from Harvard Medical School in 1968. After my residency at New York Hospital and two years as a Commissioned Officer in the Public Health Service, I was a cardiology fellow for two years at Georgetown University Hospital and a hemodynamics fellow for one year at the Washington Veterans Administration Hospital, Washington, DC. I became a staff cardiologist and the Assistant Director of the Coronary Care Unit at Georgetown University Hospital in 1975 and have held various positions at Georgetown University Hospital for the past 32 years, including Acting Chief of the Division of Cardiology and Director of the Georgetown Heart Failure Service.

3. I have regularly worked in the field of interventional cardiology since the early 1980s. I am Board-certified in Internal Medicine, Cardiovascular Disease, and Interventional Cardiology. In addition, I am a Fellow of the American College of Cardiology and the American Heart Association, and served as the President of the Nation's Capital Affiliate of the American Heart Association for two years. I have lectured and published numerous articles in the areas of heart failure, acute myocardial infarction, and interventional cardiology. I have been named one of Washingtonian Magazine's "Top Doctors" since the inception of this award, and am listed among "America's Top Physicians" by the Consumer's Research Council of America and as one of the "Best Doctors in America" by Best Doctors, Inc. A copy of my *curriculum vitae*, which includes further details on my qualifications, is attached as Exhibit A.

4. **REDACTED**

. The Washington Hospital Center employs approximately 25 interventional cardiologists and ranks among the top five hospitals in terms of the number of PCI procedures performed each year.

5. I have been retained in this matter by Medtronic Vascular, Inc. and Medtronic USA, Inc. ("Medtronic") as an expert on the clinical use of coronary stents. **REDACTED**

I testified at the trial in this case in February 2005.

6. I have been asked to opine on the relative safety, efficacy, and deliverability of certain Medtronic bare-metal stents as compared to other bare-metal stents on the United States market, and as compared to the drug-eluting stents currently on the United States market. I have also been asked to opine on the relative costs and cost-effectiveness of bare-metal stents as compared to drug-eluting stents. Finally, I have been asked to opine on the impact a court order precluding the sales of certain Medtronic bare-metal stents would have on physicians and patients.

7. Coronary artery disease is the leading cause of death in the United States. Until the development of percutaneous transluminal coronary angioplasty (“PTCA”), now usually referred to as PCI (percutaneous coronary intervention), therapy for coronary artery disease was limited to medications and coronary bypass surgery. When PTCA was introduced in the late 1970s, it was limited by two major problems: (1) acute vessel closure, or occlusion, during the procedure, often requiring emergency coronary surgery, and (2) restenosis, the process by which the treated artery becomes obstructed again over the course of several months.

8. Stents are a vital tool in the treatment of coronary artery disease. Multiple coronary stent designs were developed in the 1980s, and stents were approved for clinical use in the early 1990s for acute vessel closure and then for more general use to reduce the incidence of restenosis. The use of stents in PCI procedures has nearly eliminated the adverse consequences of abrupt occlusion and reduced restenosis rates by more than 50%.

9. In my practice as an interventional cardiologist, I have used many of Medtronic’s bare-metal stents, as well as the competing bare-metal stents sold by Abbott Cardiovascular Systems, Inc. (“ACS”), Boston Scientific Corporation, and Cordis Corporation. In my practice, the bare-metal stents of choice for the treatment of coronary artery disease are Medtronic’s Driver and MicroDriver. I prefer Driver and MicroDriver due to their flexibility, trackability, and high radial strength, among other characteristics. In my experience, Driver and MicroDriver also are substantially more flexible and deliverable than the two drug-eluting stents currently on the market.

10. Medtronic’s modular stents have thin, round struts made of an advanced cobalt-chromium alloy. In my experience, the design of these stents results in superior flexibility and allows Medtronic’s bare-metal stents to fit smoothly in the most tortuous of coronary arteries. Studies have demonstrated that the degree of vascular injury caused by the implantation of a stent influences restenosis associated with that stent. *See, e.g.*, Exhibit B at MDTI 09904,

09908-09 [C. Lally, et al., *Cardiovascular stent design and vessel stress: a finite element analysis*, J. Biomechanics, Vol. 38, 1574-81 (2005)].

11. In contrast to Driver and MicroDriver, certain other bare-metal stents, such as Boston Scientific's Liberte and Express are somewhat less deliverable because they are constructed of square, laser-cut struts that tend to scrape against the wall of narrow arteries. Although ACS's Vision and Mini Vision are very deliverable bare-metal stents, I believe that Driver and MicroDriver have superior performance characteristics. **REDACTED**

In my experience, a large number of interventionalists throughout the country also prefer Medtronic's bare-metal stents.

12. Giving physicians a broad choice of stents for the treatment of coronary artery disease is important for a number of reasons. First, a broad choice of stents mitigates the consequences of the always present risk of stent recalls. For example, ACS's Multi-Link Vision and Multi-Link Zeta bare-metal stents were the subject of three separate recalls in 2003, and Boston Scientific's bare-metal stents have been the subject of a least two Food & Drug Administration ("FDA") "Class I" recalls, with thousands of stents recalled in 1998 and 2004. True and correct copies of descriptions from the FDA's website of the three ACS stent recalls in 2003 are attached hereto as Exhibit C. True and correct copies of FDA press releases describing Boston Scientific's Class I stent recalls are attached hereto as Exhibit D. If Medtronic's bare-metal stents were enjoined and one or more of ACS's or Boston Scientific's bare-metal stents were the subject of a recall, physicians and patients could face serious clinically adverse consequences because of a shortage of needed stent devices.

13. Second, a broad choice of bare-metal stents is important because patients have widely different anatomies, plaque morphologies, and lesion distributions. While a particular brand of stent may have more desirable performance characteristics in one patient, it may have less favorable characteristics in another patient.

14. In 2003 and 2004, Cordis introduced its Cypher drug-eluting stent and Boston Scientific introduced its Taxus drug-eluting stent, respectively. These drug-eluting stents rapidly became the most commonly used stent products because they are believed to be more effective than bare-metal stents at decreasing the risk of restenosis. Between 2003 and 2005, **REDACTED**

15. However, recent studies have suggested the Cypher and Taxus drug-eluting stents may be associated with a higher risk of late and very late stent thrombosis, heart attack, and death than bare-metal stents. See Exhibit E [B. Lagerqvist, et al., *Long-Term Outcomes with Drug-Eluting Stents versus Bare-Metal Stents in Sweden*, N. Eng. J. Med., Vol. 356, No. 10, 1009-19 (2007); G. Stone, et al., *Safety and Efficacy of Sirolimus and Paclitaxel-Eluting Coronary Stents*, N. Engl. J. Med., Vol. 356, No. 10, 998-1008 (2007); M. Pfisterer, et al., *Late Clinical Events After Clopidogrel Discontinuation May Limit the Benefit of Drug-Eluting Stents*, J. Am. Coll. Cardiol., Vol. 48, 2584-91 (2006); E. Camenzind, *Safety of drug-eluting stents: insights from meta analysis.*” Presented at the European Society of Cardiology 2006 World Congress, Barcelona, September 2-6, 2006].

16. In light of these safety concerns, the FDA convened a meeting of the Circulatory System Devices Advisory Panel, which found that the Cypher and Taxus drug-eluting stents are associated with a small increase in late stent thrombosis compared to bare-metal stents that emerges one year post-stent implantation. As a result, the Advisory Panel recommended that to prevent thrombosis, drug-eluting stent patients should use aspirin indefinitely and the anti-platelet medication clopidogrel (brand name Plavix) for a minimum of 3 months (for Cypher patients) or 6 months (for Taxus patients), with therapy extended to 12 months in patients at a low risk of bleeding. Many interventional cardiologists recommend the use of dual anti-platelet therapy (aspirin + clopidogrel) indefinitely after implantation of the Taxus and Cypher stents.

17. The risk of late stent thrombosis with drug-eluting stents means that bare-metal stents increasingly will be recommended for many patients. For example, in patients with large

vessels (greater than 3.0 mm), in whom restenosis is relatively infrequent, the potential benefits of drug-eluting stents on restenosis are outweighed by the greater risk of stent thrombosis. Additionally, the concomitant need for dual anti-platelet therapy in drug-eluting stent patients increases the risk of serious bleeding. This makes drug-eluting stents a less desirable choice for patients at a high risk of bleeding and with the need for further surgeries. Drug-eluting stents are also less desirable for patients who will not take the prescribed anti-platelet medications reliably and for whom the costs of these medications are prohibitive.

18. The Cypher and Taxus drug-eluting stents also are relatively rigid as compared to the best contemporary bare-metal stents. On occasion, I have been unable to implant them successfully during a PCI procedure and have had to switch to a more flexible bare-metal stent like Driver.

19. **REDACTED**

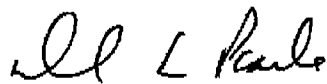
. These percentages are consistent with patterns at the high volume Washington Hospital Cardiac Catheterization Center and with figures reported nationally.

20. In addition, drug-eluting stents (and the necessary anti-platelet medications) are quite expensive. In my experience, drug-eluting stents are at least two-and-a-half times as expensive as bare-metal stents. Moreover, the need for treatment with clopidogrel within one year of implantation of a drug-eluting stent imposes significant incremental expenses, since the cost of this medication is approximately \$2.50 per daily tablet. A recent study has suggested that for patients at a relatively low risk of restenosis, bare-metal stents remain the most cost-effective stent devices on the market. *See Exhibit F [M. Eisenberg, Drug-Eluting Stents: The Price Is Not Right, Circulation, Vol. 114, 1745-54 (2006)].*

21. It is my professional opinion that a court order precluding the sales of Medtronic's Driver and MicroDriver bare-metal stents would deprive physicians and patients of what I and many other cardiologists consider to be the single best bare-metal stent on the market.

I declare under penalty of perjury under the laws of the United States that the foregoing is true and correct.

Executed on October 21, 2007, at _____.

A handwritten signature in cursive script, appearing to read "D L Pearle", written over a horizontal line.

David L. Pearle, M.D.

CERTIFICATE OF SERVICE

I, the undersigned, hereby certify that on November 8, 2007 I electronically filed the foregoing with the Clerk of the Court using CM/ECF which will send notification of such filing to Frederick L. Cottrell, III.

I further certify that on November 8, 2007 I served copies of the foregoing to the following counsel in the manner indicated:

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